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Keith et al.

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(54) **SYSTEM AND METHOD FOR DETECTING OCCLUSIONS IN A MEDICATION INFUSION SYSTEM USING PULSEWISE PRESSURE SIGNALS**

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A61M 5/142	(2006.01)
A61M 5/50	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/16854*** (2013.01); ***A61M 5/142*** (2013.01); *A61M 5/5086* (2013.01); *A61M 2005/16863* (2013.01); *A61M 2205/18* (2013.01); *A61M 2205/3355* (2013.01)

(58) **Field of Classification Search**

CPC A61M 5/142; A61M 5/16854; A61M 5/5086; A61M 2005/16863; A61M 2205/18; A61M 2205/3355; A61M 5/16831; A61M 5/16859; A61M 2005/16868; A61M 2205/3331; A61M 2005/16872; Y10S 128/12

USPC 604/506

See application file for complete search history.

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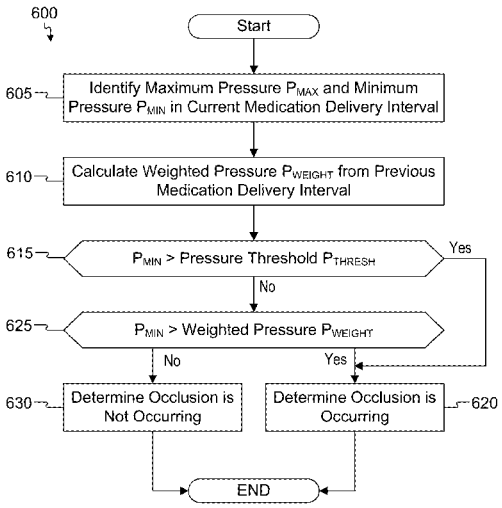
(57) **ABSTRACT**

A medical fluid communication system is disclosed comprising a pump controller and a fluid detector. The fluid detector detects characteristics of the fluid and provides fluid measurements to the pump controller, which detects if the fluid is flowing in the medication delivery system. In the event fluid is not flowing due to an occlusion, the pump controller may attempt to resolve the occlusion or may provide a warning to a user that an occlusion is occurring.

8 Claims, 9 Drawing Sheets



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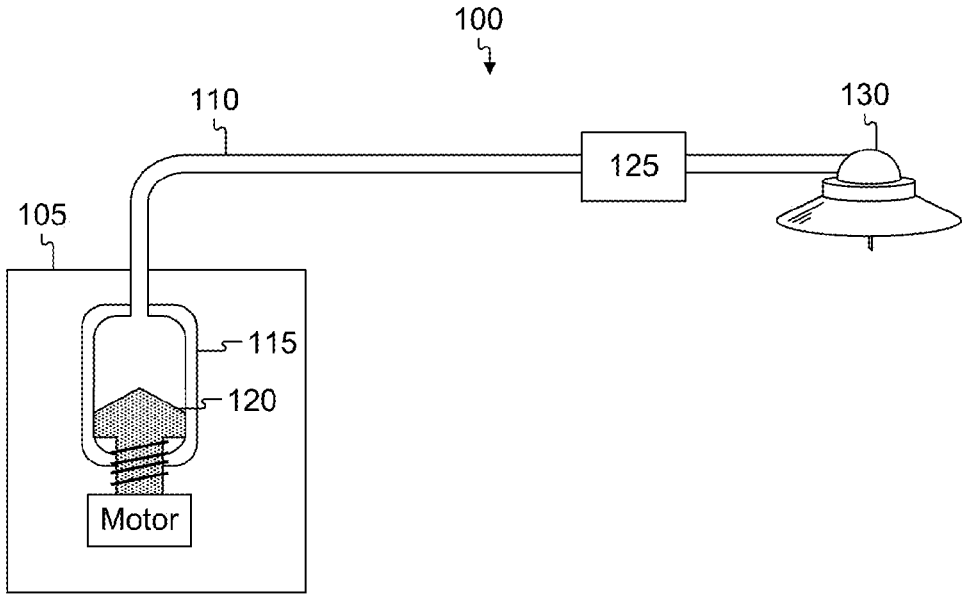
100
110
130
125
105
115
120
Motor

FIG. 1

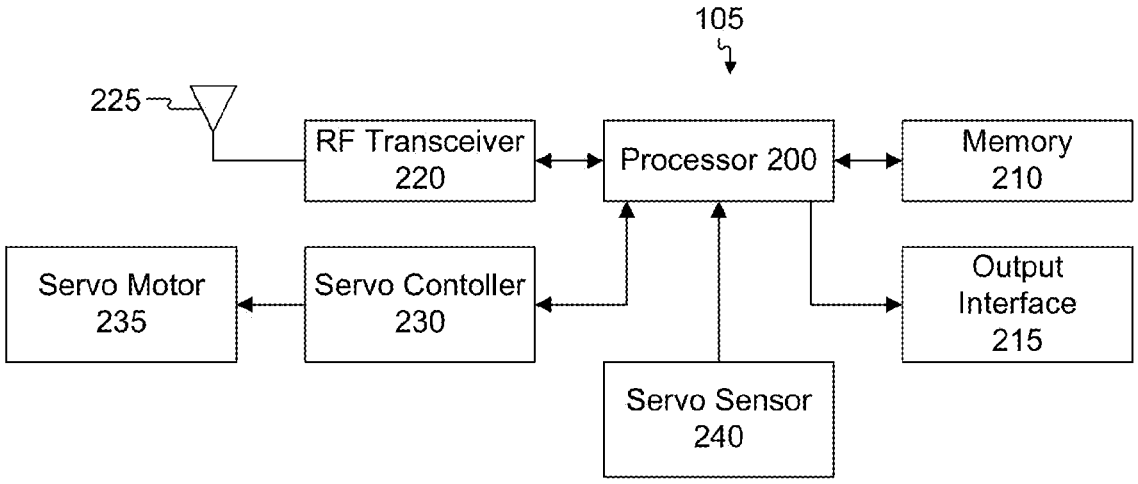
105
225
RF Transceiver 220
Processor 200
Memory 210
Servo Motor 235
Servo Contoller 230
Output Interface 215
Servo Sensor 240

FIG. 2

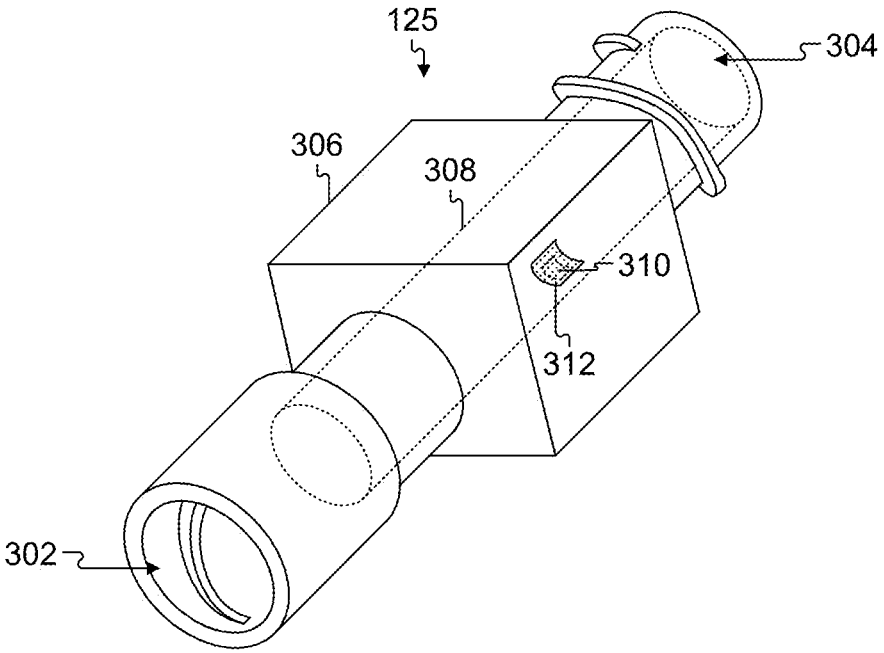
125
304
306
308
310
312
302

FIG. 3

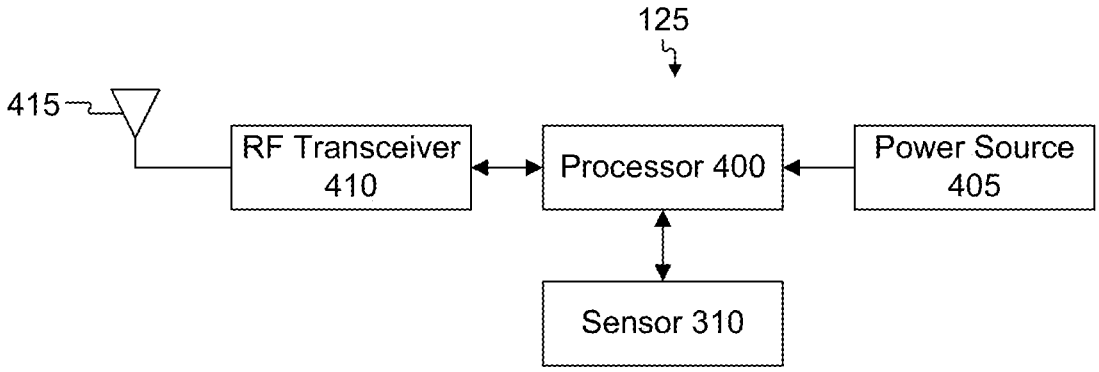
125
415
RF Transceiver 410
Processor 400
Power Source 405
Sensor 310

FIG. 4

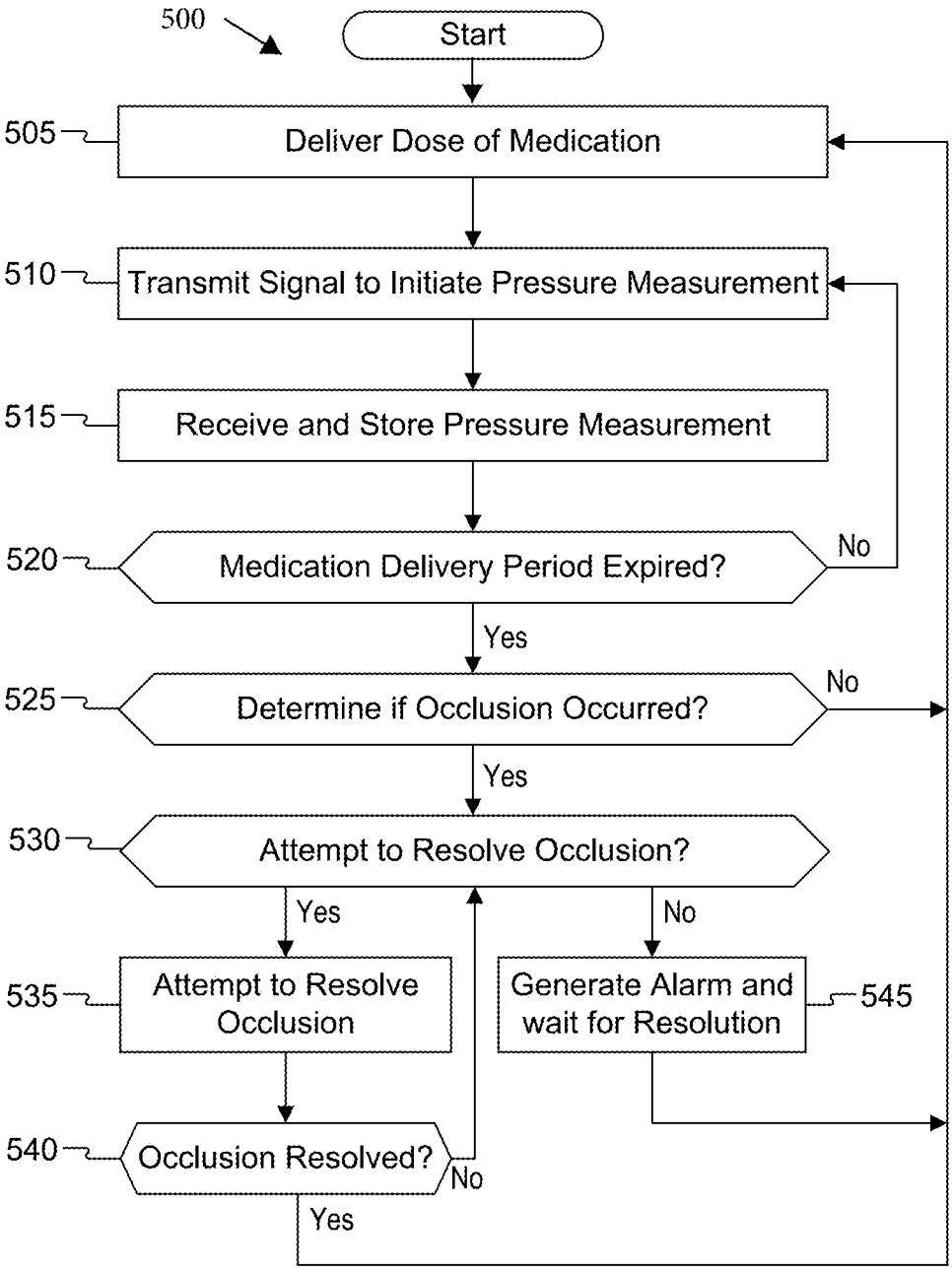
500
Start
505
Deliver Dose of Medication
510
Transmit Signal to Initiate Pressure Measurement
515
Receive and Store Pressure Measurement
520
Medication Delivery Period Expired?
No
Yes
525
Determine if Occlusion Occurred?
No
Yes
530
Attempt to Resolve Occlusion?
Yes
No
535
Attempt to Resolve Occlusion
Generate Alarm and wait for Resolution
545
540
Occlusion Resolved?
No
Yes

FIG. 5

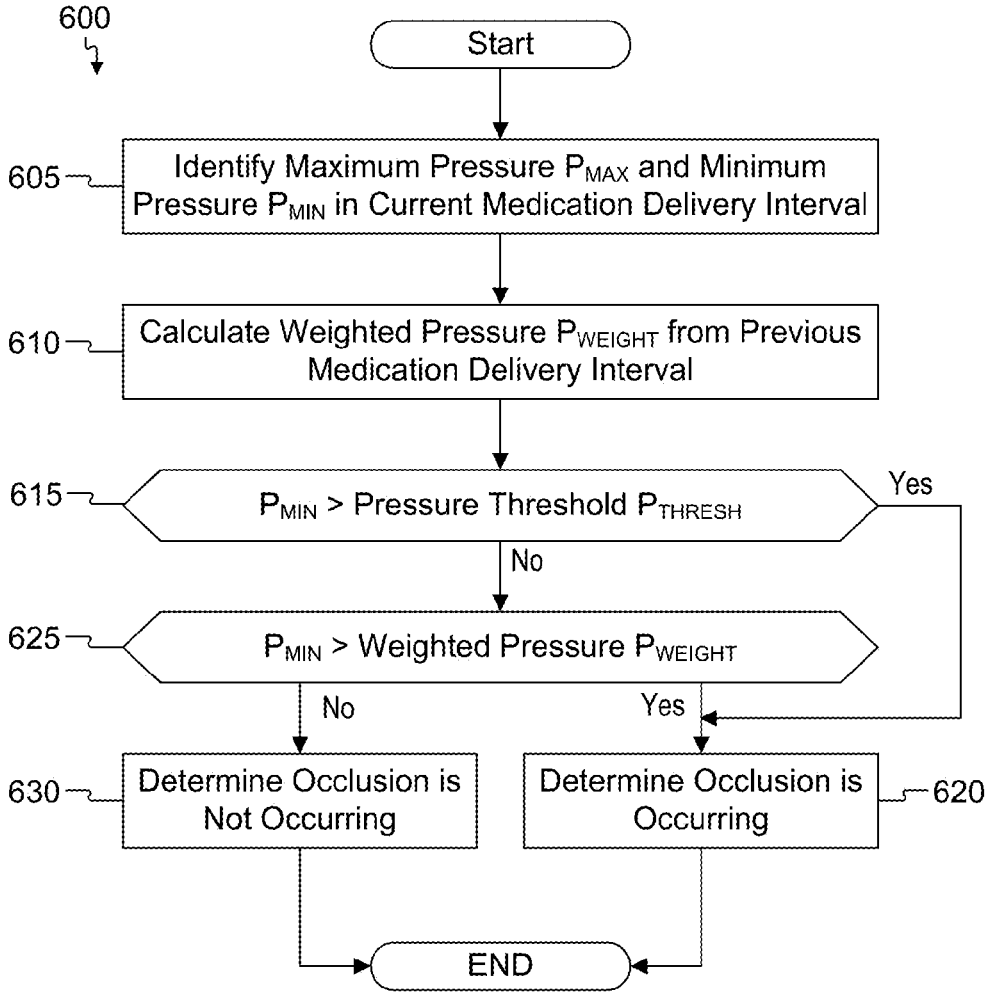
600
Start
605
Identify Maximum Pressure P_{MAX} and Minimum Pressure P_{MIN} in Current Medication Delivery Interval
610
Calculate Weighted Pressure P_{WEIGHT} from Previous Medication Delivery Interval
615
P_{MIN} > Pressure Threshold P_{THRESH}
Yes
No
625
P_{MIN} > Weighted Pressure P_{WEIGHT}
No
Yes
630
Determine Occlusion is Not Occurring
Determine Occlusion is Occurring
620
END

FIG. 6

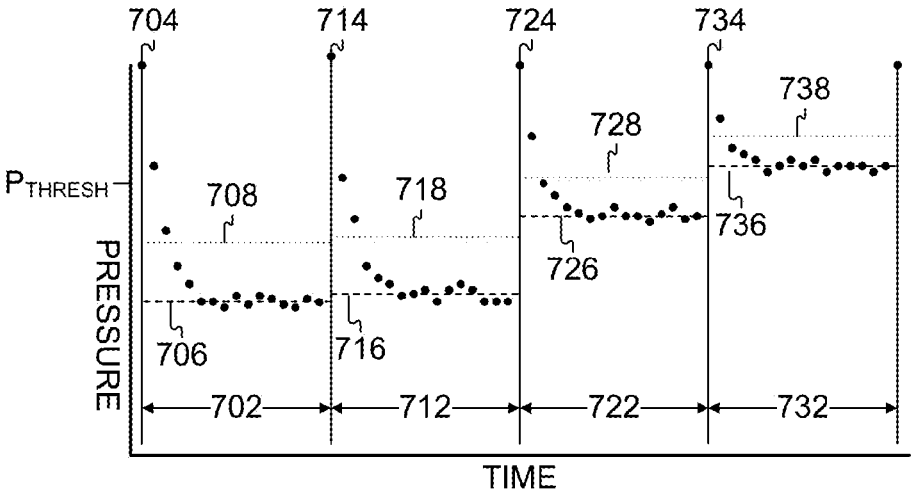
704
714
724
734
738
728
P_{THRESH}
708
718
736
726
PRESSURE
706
716
702
712
722
732
TIME

FIG. 7

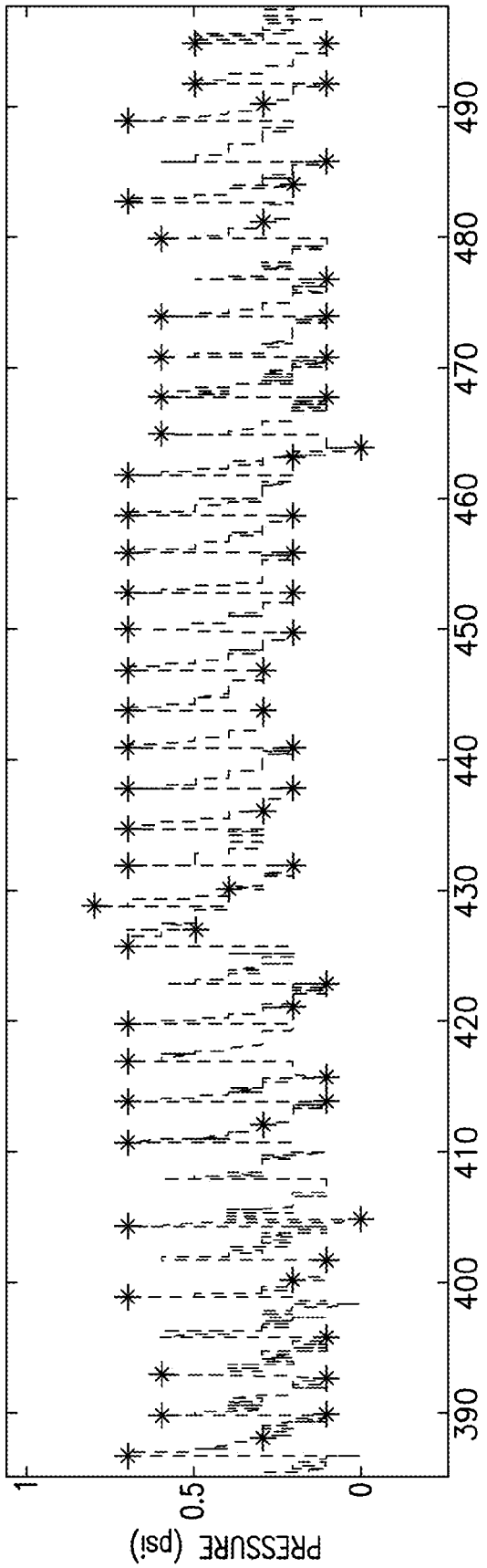
PRESSURE (psi)
1
0.5
0
390
400
410
420
430
440
450
460
470
480
490
MINUTES

FIG.8

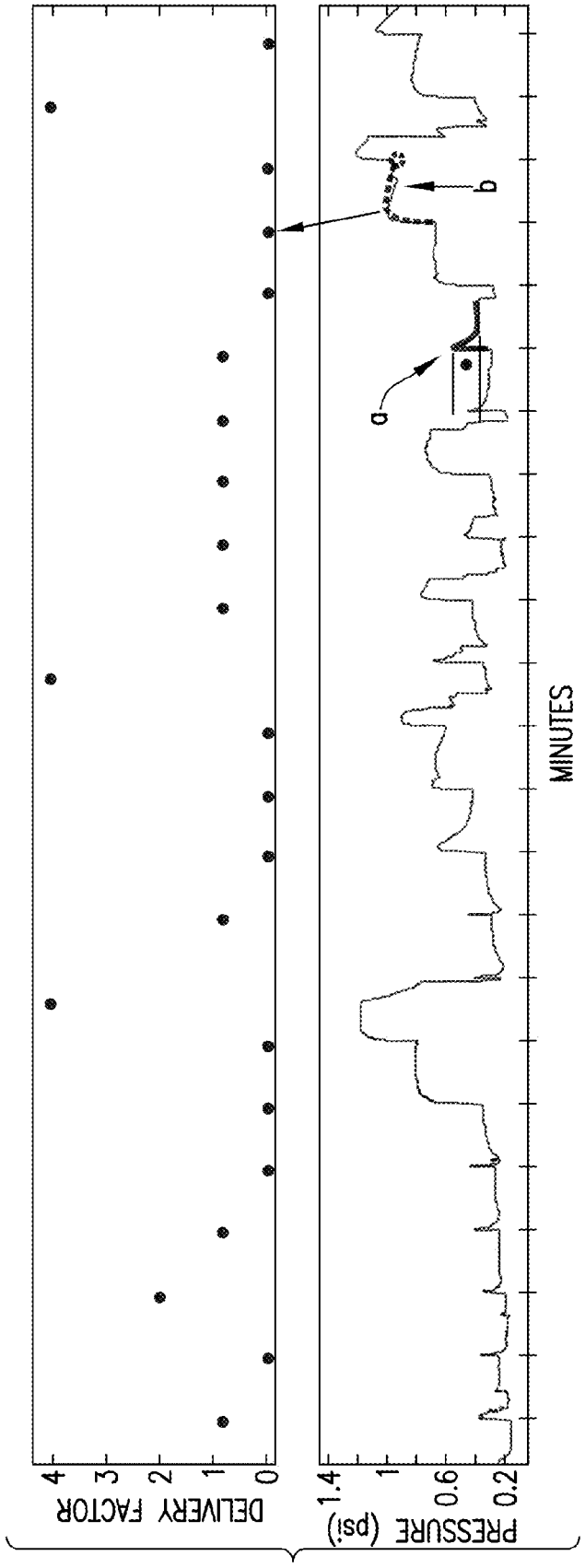

FIG.9

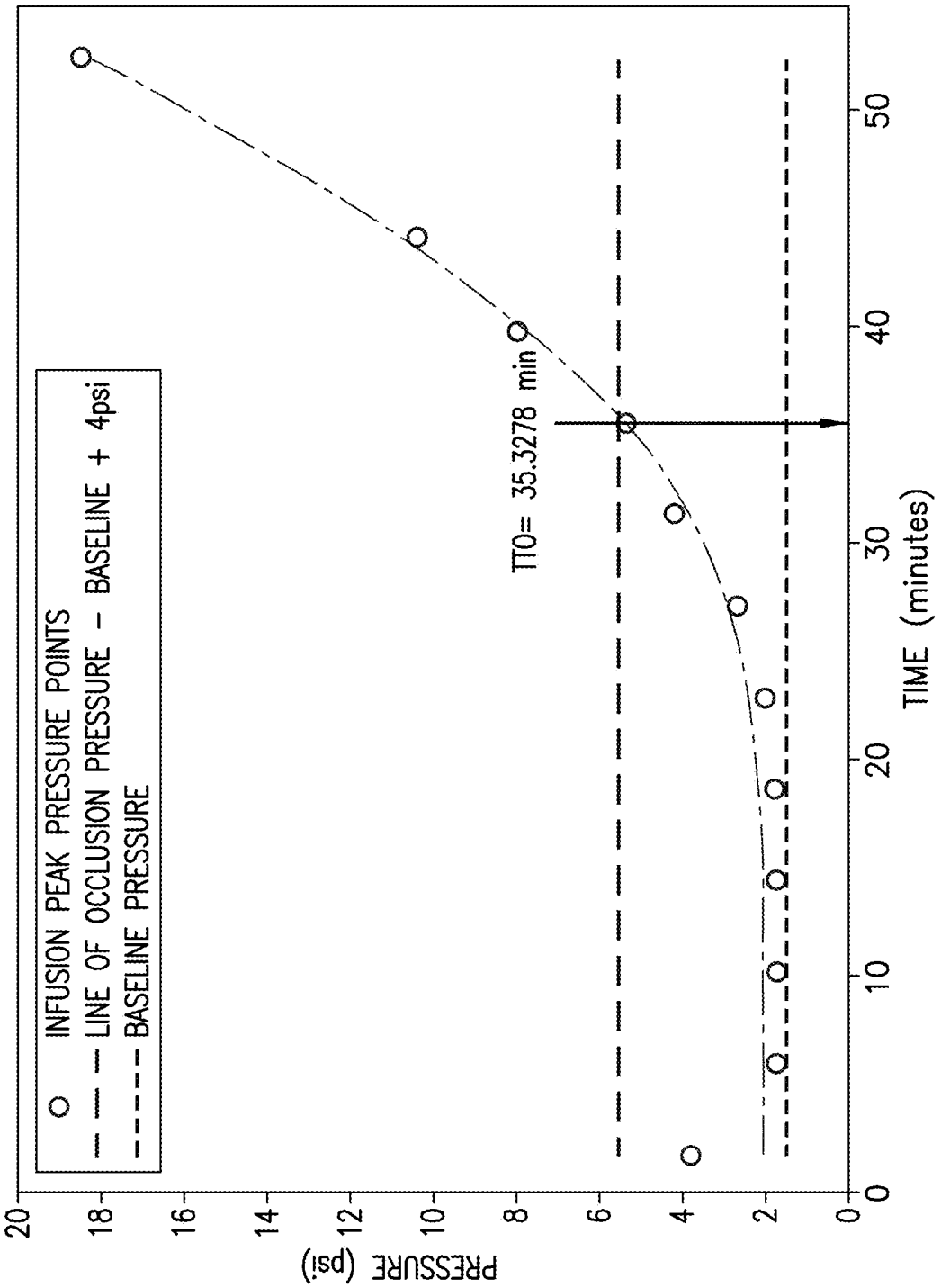
INFUSION PEAK PRESSURE POINTS
LINE OF OCCLUSION PRESSURE - BASELINE + 4psi
BASELINE PRESSURE
TTO= 35.3278 min
PRESSURE (psi)
TIME (minutes)
0
2
4
6
8
10
12
14
16
18
20
0
10
20
30
40
50

FIG.10

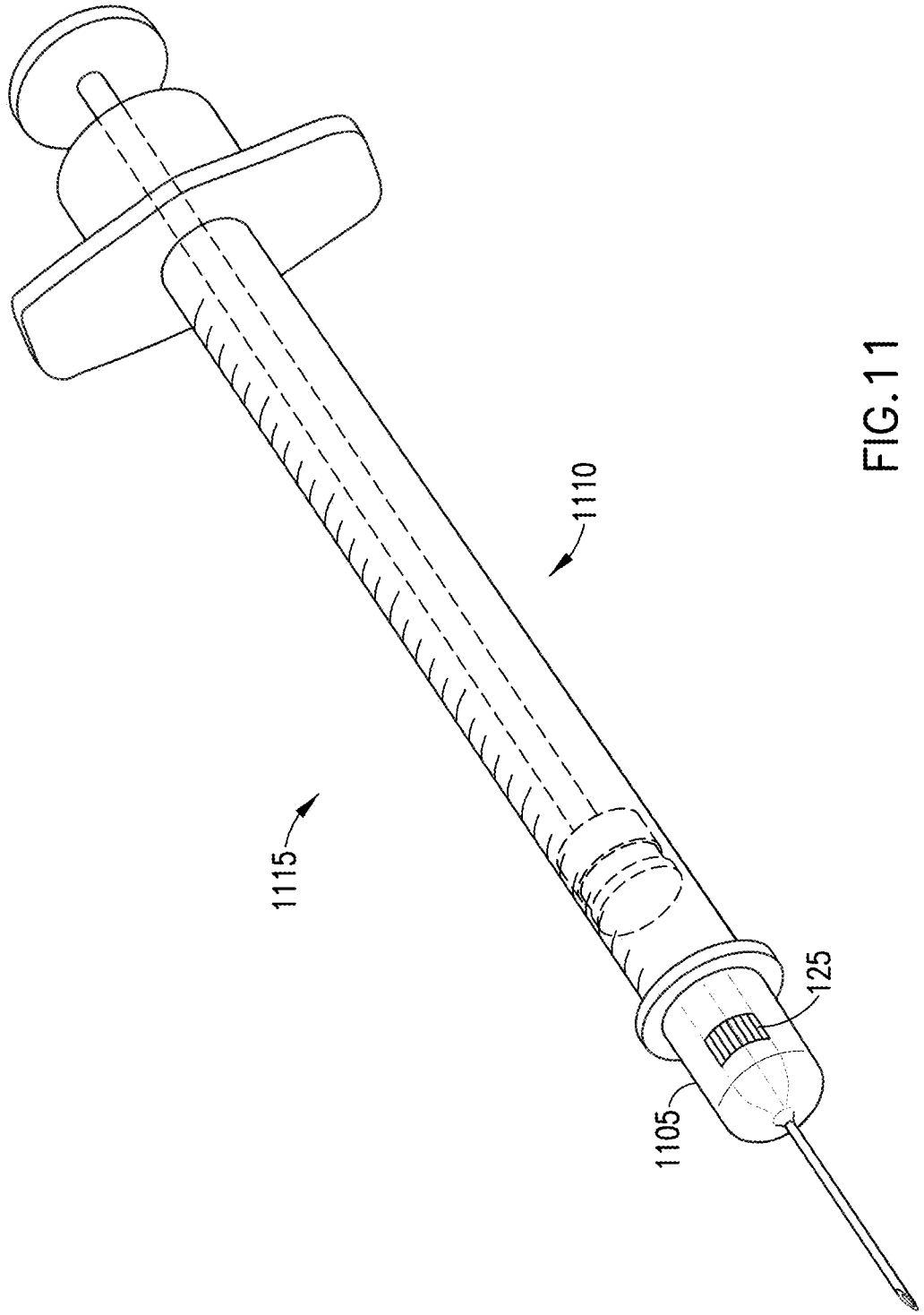

FIG. 11

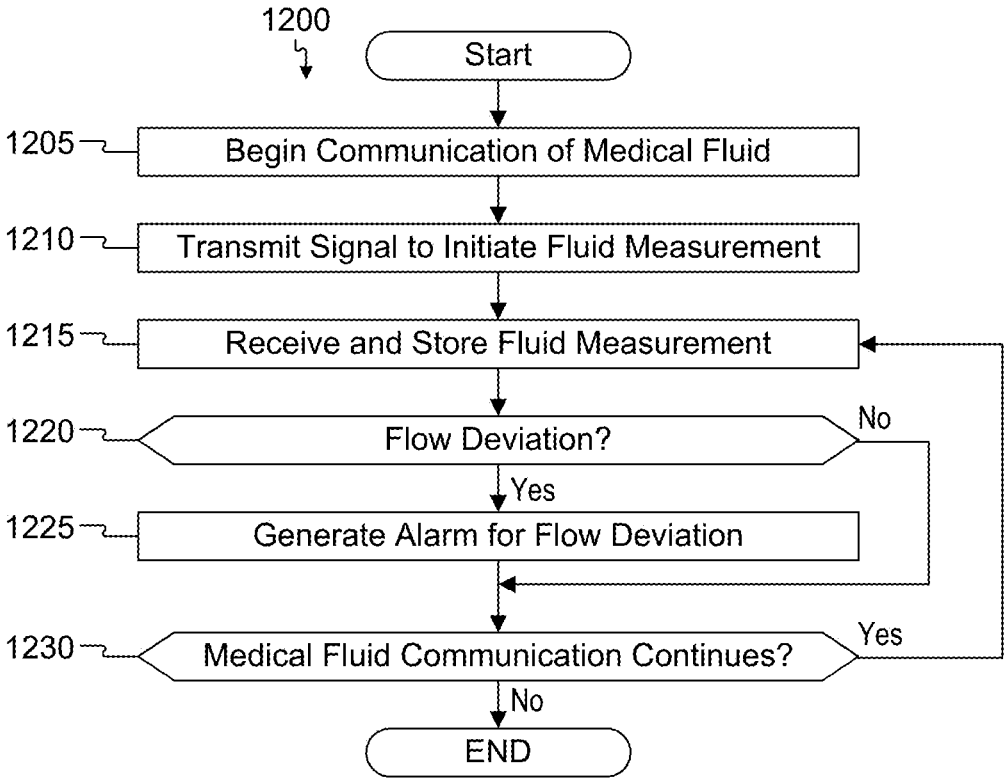
1200
Start
1205
Begin Communication of Medical Fluid
1210
Transmit Signal to Initiate Fluid Measurement
1215
Receive and Store Fluid Measurement
1220
Flow Deviation?
No
Yes
1225
Generate Alarm for Flow Deviation
1230
Medical Fluid Communication Continues?
Yes
No
END

FIG. 12

SYSTEM AND METHOD FOR DETECTING OCCLUSIONS IN A MEDICATION INFUSION SYSTEM USING PULSEWISE PRESSURE SIGNALS

This application claims the benefit under 35 U.S.C. §119 (e) of U.S. provisional application No. 61/713,096, filed Oct. 12, 2012, the entire contents of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to infusion of medication into patient and, more particularly, to a system and method for detecting occlusion in a medication infusion system using pulsewise pressure signals.

2. Description of the Related Art

Occlusion of a fluid path is a complication where either the delivery to or withdrawal of fluid from a patient is partially or completely restricted. These include devices for SC, IM, ID and intravenous (IV) delivery, access and sampling. For example, in an ambulatory insulin infusion system, both basal rate and bolus delivery of a medication fluid to a patient is typically provided by delivery of micro-boluses or fluid pulses through a fluid path (e.g., a tube) to generate the composite target total delivery volume and rate, and delivered to the patient via an infusion set. Generally, the boluses during the basal infusion are periodically delivered in short pulses over a regular interval (such as a period of 3 minutes) via a servo motor that actuates a piston. The actuated piston moves and biases the fluid in a fluid reservoir, thereby decreasing volume in the fluid reservoir and causing a controlled amount of medication fluid to flow from the fluid reservoir and into the fluid path. The infusion set receives the fluid flow and communicates the fluid into the patient. After delivering the bolus, the system waits for the period to expire to initiate a next delivery of medication. During delivery of higher volumes (such as for post-prandial meal boluses), the size of the small individual pulses may be increased and/or the time interval decreased to provide a greater total fluid volume and increased delivery rate.

As the fluid flows through the tube toward the infusion set, the induced pressure in the infusion system decays as a result of losses due to mechanical forces (e.g., static and dynamic friction, and so on). Further, other external or internal factors may further impede the flow of fluid. A partial kink in the tubing would reduce cross-sectional area in the fluid path, thereby reducing the rate of fluid able to traverse the fluid path and increasing pressure in the fluid path. The fluid path may be impeded by other factors such as crystal formation in the fluid, the presence of gaseous bubbles, impurities or other particles, backpressure from tissues in the patient, physical movement of the patient, movement of the fluid path, non-compliance of elastomeric components in the fluid path, and so on. When the fluid path is disrupted by any internal or external reason, the fluid path may experience a complete or partial occlusion that affects delivery of the medication fluid to the patient.

The flow of the medication fluid in the fluid path is currently detected by measuring the force applied to the piston during piston actuation as described above. However, the force applied to the piston can reflect static and dynamic friction forces associated with the piston mechanism in addition to pressure in the fluid path. Thus, the force applied to the piston represents the combined static friction, dynamic friction, other mechanical forces in addition to fluid pressure. The fluid pressure may in fact be a relatively small component of the overall force applied to reservoir piston, and accordingly piston force is not necessarily directly correlated to the pressure in the fluid path at the location of medication delivery. As a result, sensitivity is limited in these types of systems since the static and dynamic friction forces within the fluid reservoir dominate below approximately 2 psi. It may take multiple piston movements to determine that there is an occlusion occurring in the fluid path that is presently affecting medication delivery. Further, in the event that the pressure of the fluid reservoir is low, the static and dynamic friction forces associated with piston movement may be larger than the force required to move the liquid, thereby causing the pressure measurements during piston movement to be inaccurate and prevent detection of occlusions.

Occlusion events are responsible for premature removal of 5-15% of vascular access devices such as peripheral intra venous catheters (PIVCs) that are used both for patient fluid sampling and medication delivery. Evidence suggests that timed or scheduled removal of PIVC catheters without cause may not benefit patients and may add cost to healthcare treatment. In a PIVC catheter, occlusion may be a result of mechanical phenomena such as kinking or impingement of the catheter tip against the intima, biochemical effects such as precipitation of the infusate, and thrombus formation. In particular, thrombus aggregation in a catheter may cause an occlusion event that leads to other complications such as phlebitis. In a PIVC catheter, blood can enter the catheter during events such as placement of the catheter, as a result of pressure changes from movements of the catheter or associated tubing, during checks performed by medical staff, as a result of improper or incomplete flushing of the catheter, or via blood sampling. Each blood exposure event in the catheter can lead to build up of thrombus within or around a catheter to form a clot that reduces the diameter of the flow path. Consequently, more pressure is needed to deliver the same amount of fluid at a given rate with potentially dangerous consequences for the patient.

In conventional systems an occlusion in the fluid path may be detected too slowly or not at all in some circumstances, with potentially dangerous consequences for the patient. For instance, if an undetected occlusion occurs during insulin infusion, the patient may not receive a necessary amount of medication to prevent a potentially dangerous hyperglycemic event. Because the delivery of the medication fluid may be vital in delivery of medical service, there is a need for rapid detection of occlusions in medication delivery systems.

SUMMARY OF THE INVENTION

Disclosed is a system and method for detecting occlusions in a medication fluid communication system or venous access device comprising a fluid reservoir, a fluid path connected between the fluid reservoir and a patient, a fluid delivery mechanism, and a pressure sensor measuring a pressure of the fluid within the fluid path. The method includes measuring pressure of a medication fluid in a fluid path of a medication delivery system during a current interval. Based on the pressure measurements, the method determines if a flow of the medication fluid is successful, reduced, or unsuccessful.

Also disclosed is another system and method for detecting occlusions in a medical fluid communication system having a fluid reservoir, a fluid path connected between the fluid reservoir and a patient, a fluid delivery device, and a

pressure sensor measuring a pressure of the fluid within the fluid path. The method measures a pressure of a medication fluid in a fluid path of a medication fluid communication system during a current interval and compares the minimum pressure of the current interval to a predetermined threshold pressure. The predetermined threshold is based on a calculation of a peak pressure of the previous interval and a minimum pressure of the previous interval. The method determines if a flow of the fluid is not successful if the minimum pressure exceeds the predetermined threshold and determining if the flow of the medical fluid is successful if the minimum pressure does not exceed the predetermined threshold.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

These and other features and advantages of the present invention will become more apparent from the detailed description of exemplary embodiments with reference to the attached drawings in which:

FIG. **1** illustrates and example medication delivery system in accordance with an exemplary embodiment of the present invention;

FIG. **2** depicts a block diagram of an example pump controller of the medication delivery system of FIG. **1**;

FIG. **3** is a perspective view of an example fluid detector of the medication delivery system of FIG. **1**;

FIG. **4** depicts a block diagram of an example fluid detector of the medication delivery system of FIG. **1**;

FIG. **5** illustrates a flowchart of an example process that the medication delivery system may implement in accordance with an exemplary embodiment of the present invention;

FIG. **6** illustrates a flowchart of an example method of determining that an occlusion occurred during a medication delivery interval in connection with the example process described in FIG. **5**;

FIG. **7** illustrates an example chart of pressure measurements over four medication delivery intervals;

FIGS. **8** and **9** illustrate data comparing pulses to provide an indication of flow status of the fluid path using the example process described in FIG. **5**;

FIG. **10** illustrates data comparing peak pressure data within the peripheral IV catheter recorded during an IV infusion according to an exemplary embodiment of the invention;

FIG. **11** depicts another example fluid detector in a needle hub of a syringe used in the medication delivery system of FIG. **1**; and

FIG. **12** illustrates another flowchart of an example process that the medication system may implement in accordance with an exemplary embodiment of the present invention.

Throughout the drawings, like reference numerals will be understood to refer to like features and structures.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Reference is now made in detail to exemplary embodiments of the invention, which, together with the drawings and the following examples, serve to explain the principles of the invention. Those of ordinary skill in the art will appreciate that the embodiments described herein are merely exemplary, and are described in detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized, and various changes to the embodiments described herein may made without departing from the spirit and scope of the present invention. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the example methods, devices and materials are now described.

FIG. **1** illustrates an example medication delivery system **100** that detects partial or complete occlusions during delivery of medication fluid to a patient or sampling or withdrawal of fluid from a patient. The medication delivery system **100** generally operates by delivering minute boluses (such as 0.5 microliters) to a patient over a short pulse (such as 100 milliseconds, 1 second, and so on) at regular intervals (such as a period of 3 minutes, or the like). The medication delivery system **100** includes a pump controller **105** that delivers a pulse of medication fluid to a patient via a fluid path such as tubing **110**. In the example of FIG. **1**, the pump controller **105** includes a fluid reservoir **115** containing the medication fluid. In this example, the fluid reservoir **115** is configured to interface with a piston **120** that is mechanically displaced within the fluid reservoir **115** by any suitable mechanism, such as a servo motor. In other examples, any device suitable for delivering controlled dosages of fluid could perform the medication fluid delivery. By actuating the piston **120**, the piston **120** is axially displaced within the fluid reservoir **115**, and thereby reduces the available volume within the fluid reservoir **115**. As such, the pressure within the fluid reservoir **115** increases and causes a controlled volume of the medication fluid to flow into the tubing **110** toward the patient. That is, a pressure pulse, which causes the medication fluid to flow, travels from the fluid reservoir **115** through the tubing **110** at a velocity that depends on the characteristics of the fluid path, the medication fluid, and so forth.

The medication delivery system **100** includes a fluid detector **125** that receives and measures characteristics of the pressure pulse in the medication fluid to determine if it is flowing in the medication delivery system **100** and being delivered to the patient. In the example of FIG. **1**, the fluid detector **125** is placed inline with tubing **110** and in proximity with an infusion set hub **130** containing an infusion cannula that delivers the medication fluid into the patient.

That is, the fluid detector **125** is in fluid communication with the tubing **110**, the fluid reservoir **115**, and the infusion set hub **130**. Preferably, the fluid detector **125** is placed in proximity to the infusion set hub **130** to measure the pressure of the medication fluid close to the location of medication delivery to the patient. In other examples, the fluid detector **125** may be integrated within the infusion set hub **130**. Alternatively, the fluid detector **125** may be disposed adjacent to or integrated within the fluid reservoir **115**. In another example, multiple fluid detectors **125** may be implemented at several positions along the fluid path to detect pressure at different locations of the fluid path.

The fluid detector **125** receives the medication fluid and measures any suitable characteristic of the fluid such as pressure, temperature, force, flow rate, volume, conductance, resistance and so forth. The fluid detector **125** then communicates the measurement results to the pump controller **105**, which uses the fluid measurements to determine if the medication fluid is sufficiently flowing in the fluid path and being delivered to the patient. In one example, the fluid detector **125** may transmit the fluid measurements to the

pump controller **105** via a wireless interface. In other examples, the fluid detector **125** may transmit the measurements via a wired interface, such as an electrical conductor embedded in the tubing **110**, or the like.

FIG. **2** illustrates a block diagram of an example pump controller **105** that controls the operation of the medication delivery system **100** by receiving the measurements from the fluid detector **125** shown in FIG. **1**. In the example of FIG. **2**, a processor **200** receives the fluid measurements via any suitable interface, such as an analog-to-digital converter, a modulated input, or the like. The fluid measurements are stored in a memory **210** which can be separate or integral with the processor **205**. Using the fluid measurements, the processor **205** determines if an occlusion has occurred and generates an output via output interface **215** to provide notice of the occlusion. The output interface **215** is generally any output mechanism that displays a warning to a health care professional or patient to provide notice of an occlusion. For instance, the pump controller **105** may include a liquid crystal display (LCD) that outputs pressure measurements to the health care professional and, in the event an occlusion is determined to be occurring, can output a display indicator on the LCD to provide such notice. In other examples, a light emitting diode (LED) may be activated or modulated, an audible event such as an alarm may be output, or a haptic event such as a vibration via a vibration motor (not shown) via the output interface **215**.

The example pump controller **105** of FIG. **2** includes a RF transceiver **220** for sending and receiving data to and from the fluid detector **125** via an antenna **225**. In such an example, the RF transceiver **220** may be implemented by a custom application specific integrated circuit (ASIC) or may be implemented by over-the-shelf solutions, such as Zigbee®, Bluetooth®, or any other suitable method.

The pump controller also includes a servo controller **230** for actuating a servo motor **235** for driving the piston **120** to cause fluid to flow from the fluid reservoir **115**. In other examples, the servo controller **230** may be integral with processor **200**. Further, the pump controller **105** may also include a servo sensor **240** to detect pressure applied to the piston during piston **120** movement during medication delivery.

FIG. **3** is a perspective view of an exemplary in-line fluid detector **125** that is potentially implemented via a standard inline medical connector such as a Luer-Lok®, Safety-Lok®, or any other suitable connector. That is, the fluid detector **125** includes a female connector **302** disposed at a proximal end and a male connector **304** disposed at a distal end to allow the fluid detector **125** to be connected inline between the tubing **110** and the infusion set **130**. The fluid detector **125** includes a mechanical housing **306** disposed between the female connector **302** and male connector **302** and includes a fluid path **308** to permit fluid flow and to detect a property of the flowing fluid, such as the pressure of the fluid.

The fluid path **308** includes a sensor **310** that detects a suitable characteristic of the fluid such as pressure. In other examples, the pressure may be measured in conjunction with other characteristics to improve fluid detection, such as temperature, viscosity, or any other suitable characteristic. In the example of FIG. **3**, the sensor **310** is substantially encapsulated by a shield **312**, preferably constructed of a polymer, or the like, to physically isolate the sensor **310** from the fluid path and prevent any contact with the medication fluid. However, in other examples, the sensor **310** may directly contact the medication fluid. In the example of FIG. **3**, the sensor **310** is a strain gauge that detects pressure of the medication fluid in the fluid path **308**. Thus, to provide the most accurate pressure measurements, the fluid detector **125** is preferably placed close to the infusion set to provide the most accurate pressure measurement of the medication fluid flow. In other examples, the sensor **310** may be implemented by any suitable mechanism to detect the suitable characteristic of the fluid, such as an electromagnetic pressure sensor, a piezoelectric sensor, an optical sensor, a potentiometric sensor, a thermal sensor, or any other suitable characteristic sensor.

In other examples, the fluid detector **125** may be integrated within the infusion set hub, thereby detecting flow of the medication fluid at the location of delivery to a patient. In another example, the fluid detector **125** may include a standard or proprietary connector adapted to receive both medication fluid and electrical signals in a single integral connector. In such an example, the fluid detector **125** may be adapted to send the measurement data as electrical data via tubing **110** having electrically conductive members therein that are isolated from the fluid path. Further, such electrical signals provided via the conductive members may be configured such that medication fluids are not affected by the data transmission. In other words, the medication fluid is preferably isolated from electromagnetic fields, and the like.

FIG. **4** illustrates an example block diagram of a fluid detector **125** disposed in the mechanical housing **306** and detects characteristics of the fluid in fluid path **308** as described in detail above. The fluid detector **125** includes a processor **400** that is implemented by any suitable device for detecting the measurements of the sensor **310** and providing the results to the pump controller **105**, such as a logic circuit, an ASIC, an FPGA, a microcontroller, a microprocessor, or the like. That is, the sensor **310** is coupled to an input on the processor **400**. Generally, a highly integrated processing device such as a microcontroller having an integrated analog-to-digital converter and memory is preferred due to advantageous size and power characteristics. The processor **400** is configured to receive power from an power source **405** of the fluid detector **125** that may be integral or extrinsic. In other examples, the integral power source **405** may be provided via inductive coupling to an inductor that receives wireless signals and converts the magnetic field into electric power.

The fluid detector **125** also preferably includes a RF transceiver **410** that sends and receives data via antenna **415**. In one example, the fluid detector **125** may receive an instruction to measure the fluid pressure via a wireless transmission from the pump controller **105**. In response, the processor **400** may induce the sensor **310** to provide a measurement on at least one input. For example, in the event the sensor **310** is implemented via a strain gauge in the fluid path **308**, a first voltage is applied to the sensor **400** via an output of processor **400**. An input of processor **400** receives second voltage that is reduced via the electrical resistance of the strain gauge and calculates the strain pressure applied to the sensor **310**. Further, the processor **400** may calculate a normalized pressure based on a nominal strain pressure to determine the pressure of the fluid in the fluid path **308**. Of course, the sensor **310** need not receive specific commands for measuring a fluid characteristic, and may instead simply make measurements at predetermined intervals, and provide measurements to the processor **400**.

By having an in-line sensor **310**, the sensitivity of fluid characteristic measurement is increased. As will be appreciated, an in-line pressure sensor directly measures fluid pressure, as opposed to a force measurement device coupled to a piston **120** within a reservoir **115**, eliminating the

sometimes dominating force components contributed by static and dynamic friction, and the like, associated with the piston.

FIG. **5** illustrates an example process **500** for detecting occlusion in the medication delivery system during treatment of a patient. Generally, a medication delivery interval begins with a delivery of a dose of the medication fluid and continues until the next medication delivery occurs. Initially, at step **505**, the example process **500** and the medication delivery interval begin by delivering a dose of medication fluid at step **505**. In one example, the pump controller then transmits a signal to initiate a pressure measurement in the fluid path at step **510**. In response, the fluid detector measures the fluid pressure in the fluid path and transmits the pressure measurement to the pump controller, which stores the pressure measurement at step **515**. After receiving the pressure measurement, the example process **500** determines if the current medication delivery interval has expired at step **520**. If the current medication delivery interval has not expired at step **520**, the example process **500** returns to step **510** to transmit a signal to initiate and receive the next pressure measurement in the current medication delivery interval.

If the current medication delivery interval has expired at step **520**, using the pressure measurements, the example process **500** determines if an occlusion occurred during the current medication delivery interval occurred at step **525**. If an occlusion did not occur at step **525**, the example process **500** returns to step **505** to initiate a next medication delivery interval that begins with delivering a next dose of the medication fluid.

If an occlusion is determined to have occurred at step **525**, the example process **500** may determine if there should be an attempt to resolve the occlusion based on any suitable criteria at step **530**. For example, if the maximum pressure exceeds a predefined pressure during a single medication delivery interval, the example process **500** may determine it should attempt to resolve the occlusion at step **535**. For example, the example process **500** may generate a very large transient pressure peak by actuating the piston and increasing the rate at which the piston moves. Alternatively, an increased amount of medication fluid is delivered to the patient and the pressures of the medication fluid are measured at various times and then compared after a period of time. In another example of step **535**, a drug-free fluid connected to the fluid path as close as possible to the infusion set, which may be delivered such that the drug-free fluid passes through the infusion set and through the delivery location of the patient. Such an example allows the smallest possible amount of medication fluid to be delivered to the patient. In such an example, this medication clearing event could be accompanied by or preceded by a small movement of the piston in the negative direction, that is, increasing the volume in the fluid reservoir such that pressure is normalized, thereby preventing over-medicating the patient. In another example, the infusion set may be manipulated by a high frequency displacement of the infusion set tip by, for example, motion of a piezoelectric device located in the infusion set body or by manual manipulation by the patient or medical professional.

After attempting to resolve the occlusion at step **535**, the example process continues at step **540** to determine if the occlusion is resolved. In the event the occlusion is resolved at step **540**, the example process **500** returns to step **505** to deliver the next suitable dose of medication in the next appropriate medication delivery interval. For example, process **500** may wait a period of time after resolving the occlusion. On the other hand, if the occlusion is not resolved at step **540**, the example process **500** returns to step **530** to determine if it should attempt to resolve the occlusion.

In the event that the example process **500** determines to not attempt resolution of the occlusion at step **530**, the example process **500** generates an alarm and waits for resolution of the occlusion at step **545**. For example, a message may be output to request the patient to physically manipulate the infusion set to clear an occlusion due to a partial kink and then provide an input to signal that the occlusion event is resolved. In such an example, after the occlusion is resolved by any suitable corrective action, the example process **500** returns to step **505** to deliver the next suitable dose of medication in the next suitable medication delivery interval.

That is, the example process **500** at steps **530-545** waits until the occlusion is resolved before continuing medication delivery. In some examples, after returning to step **505**, the example process **500** would continue to compare the pressure measurements with previous pressure measurements prior to the occlusion event to ensure correct delivery of medication. However, in other examples, the example process **500** may flush the previous pressure measurements based on a change in the system that does not substantially affect delivery of the medication, such as a partial occlusion due to the configuration of the fluid path, such as tangling in clothing, for example.

One example implementation of the example process **500** may be a drug delivery feedback system implementing an artificial pancreas. In such an example, knowledge of insulin delivery status will improve delivery of insulin to the patient using real-time insulin delivery data based on the pressure measurements at the fluid detector. Even without knowledge of the concentration of the dosage, the example process **500** uses previous insulin delivery volumes to calculate the preferred delivery volume of medication for the patient at any time. Thus, data regarding incomplete or missing delivery of the insulin would improve performance of such an example system.

Generally, at least two pressure measurements must be measured in each medication delivery interval. In such an example, the example process **500** attempts to measure the actual peak pressure that occurs at the beginning of the medication delivery interval and a minimum pressure that occurs in the latter portion of the medication delivery interval. In other examples, the pressure measurements may be aperiodic to allow the example process **500** to measure at different intervals in the medication delivery interval to allow for rapid detection of occlusions.

Further, although the described example process **500** detects occlusions after the medication delivery interval expires, the example process **500** may be adapted to detect occlusions during medication delivery intervals. For instance, if the peak pressure or the minimum pressure of the fluid exceeds a predefined threshold, the example process **500** may determine that an occlusion has occurred in the current medication delivery interval. Further, if a subsequent peak pressure is greater than a previous peak pressure by a predefined threshold, the example process **500** may generate an alarm and halt further delivery of the medication fluid before the medication delivery interval expires.

FIG. **6** illustrates an example process **600** for determining if an occlusion has occurred during the medication delivery interval, as briefly described in connection with FIG. **5**. Initially, the example process **600** identifies a maximum pressure P_{MAX} and a minimum pressure P_{MIN} from the current medication delivery interval at step **605**. The maxi-

mum pressure P_{MAX} occurs during the delivery phase of the medication and pressure decays in the relaxation phase until it reaches equilibrium where the minimum pressure P_{MIN} for the current medication delivery interval is generally determined. That is, the maximum pressure P_{MAX} generally occurs at the beginning of each medication delivery interval. However, in some situations, such as an occlusion event during a movement, the maximum pressure P_{MAX} may occur at any point during a medication delivery interval. Generally, the minimum pressure P_{MIN} is filtered and/or averaged over several delivery pulses to remove noise in the measurements. Moreover, as will be described further below, an occlusion may be recognized by subsequent P_{MIN} measurements increasing in magnitude, indicating increasing pressure due to multiple delivery pulses failing due to the occlusion and causing fluid pressure to rise.

At step **610**, the example process **600** calculates a weighted pressure P_{WEIGHT} from a previous medication delivery interval. Specifically, weighted pressure $P_{WEIGHT}=W*P_{MAX}+(1-W)*P_{MIN}$ where W is a weighting factor, such as 0.25, that determines the sensitivity of the occlusion detection, P_{MAX} is the maximum pressure from a previous medication delivery interval, and P_{MIN} is the minimum pressure from the previous medication delivery interval. In one example, the previous medication delivery interval is two intervals before the current medication delivery interval. However, in other examples, multiple previous medication delivery intervals may be used to generate the weighted pressure P_{WEIGHT} in any suitable fashion, that is, by multiple comparisons, averaging the measurements, generating a detection window that adjusts based on the magnitude of the maximum pressure, and so forth. In other examples, the sensitivity may be variably adjusted based on suitable factors to ensure accurate detection of occlusions. For example, if the minimum pressure P_{MIN} is sufficiently low due to the viscosity of the liquid and the maximum pressure P_{MAX} is large, the sensitivity can be increased by adjusting the weighting factor W to account for more subtle changes in the minimum pressure P_{MIN}. Further, it should be appreciated that the method is not limited to analyzing a set of consecutive intervals indicating a problematic flow state. That is, the method should be understood to include embodiments that can accommodate intervening intervals indicating successful flow.

After calculating the weighted pressure P_{WEIGHT}, the example process **600** compares the current minimum pressure to a predetermined threshold pressure P_{THRESH} (e.g., 3 psi) at step **615**. In the event that the minimum pressure exceeds the threshold pressure P_{THRESH}, the example process **600** determines that an occlusion is occurring at step **620** and exits. If the minimum pressure does not exceed the threshold pressure P_{THRESH}, the current minimum pressure is compared to the weighted pressure P_{WEIGHT} at step **625**. If the current minimum pressure exceeds the weighted pressure P_{WEIGHT}, the example process **600** determines that an occlusion is occurring at step **620** and the example process **600** ends. However, if the current minimum pressure does not exceed the weighted pressure P_{WEIGHT}, the example process **600** determines that an occlusion is not occurring at step **630** and the example process **600** ends.

In another example, another exemplary method of determining if an occlusion has occurred during the medication delivery interval, as briefly described in connection with FIG. **5**, may be performed by observing large fluctuations. In such an example, the method compares the current pressure profile to a smoothed profile, such as a smoothing spline fit, and tracks measurement events that deviate significantly from the smoothed curve. Using a standard deviation of pressure measurements over a period time, flow of the medication of fluid is determined to be unsuccessful if the measured pressure exceeds two standard deviations for a suitable period of time, such as 3 minutes.

As noted above, the pump controller **105** compares current pressure measurements in a medication delivery interval with relevant information to determine if an occlusion is occurring. FIG. **7** illustrates a graph of example pressure measurements in an examplary medication delivery system **100** during delivery of medication to a patient and illustrates different techniques to determine if an occlusion occurs. That is, FIG. **7** is not representative of actual data and is provided to facilitate how the medication delivery system **100** can detect occlusions.

At the beginning of a medication delivery period **702**, the medication delivery system **100** actuates the piston **120** to force medication in a fluid reservoir **115** to be delivered to the patient. As a result, the pressure increases in the tubing **100** and traverses toward the delivery location of the medication. In the example of FIG. **7**, measurement **704** illustrates that the pressure increases at the fluid detector **125** during the initial delivery of the medication and, therefore, the maximum pressure **704** (P_{MAX}) occurs at the beginning of medication delivery period **702**. Generally, the medication delivery system is configured to record the actual maximum pressure that occurs in the fluid path. In some examples, the medication delivery system **100** may begin recording pressure data before the expected maximum pressure occurs at the fluid detector.

As illustrated in medication delivery interval **702**, the pressure decays at the fluid detector **125** after delivery of the medication in a decay region and returns to an equilibrium region where a minimum pressure P_{MIN} **706** of the medication delivery period is determined. Generally, as illustrated in FIG. **7**, the minimum pressure occurs in the latter portion of the medication delivery interval **702**. The weighted pressure **708** can be determined using the maximum pressure **704**, minimum pressure **706**, and a weighting factor (e.g., 0.25) as described above.

In the second medication delivery interval **712**, the maximum pressure **714** is substantially equal to the maximum pressure **704** and the minimum pressure **716** is substantially equal to the minimum pressure **706**. As such, no occlusion is detected in the second medication delivery interval **712** based on the weighted pressure **708** of the first medication delivery interval because the minimum pressure **716** does not exceed the weighted pressure **708** of the first medication delivery interval **702**.

In the third medication delivery interval **722**, the maximum pressure **724** is substantially equal to the maximum pressure **704**. However, the minimum pressure **726** increases substantially such that it exceeds the weighted pressures **708** and **718** of the previous medication delivery intervals **702** and **712**. That is, the example process **600** would detect an occlusion in the third medication delivery interval **722** because the minimum pressure **726** exceeds at least one of the weighted pressures **708** and **718**. As noted above, the example process **600** uses any suitable weighted pressure to detect an occlusion in the current medication delivery interval.

For the purposes of the fourth medication delivery interval **732**, the effect of the detected occlusion in the third medication delivery **732** is ignored for further explanation. In fact it may be desirable for the detection method to ignore some initial number of "occlusion events" in order to eliminate noise and permit temporary occlusions to work

themselves out without generating an alarm. Such a method would preferably set a minimum number of consecutive "occlusion event intervals" to be determined prior to determining that an occlusion has actually occurred. In the fourth medication delivery interval **732**, the maximum pressure **734** is substantially equal to the maximum pressure **704**. However, the minimum pressure **736** increases substantially such that it exceeds the pressure threshold P_{THRESH}. Thus, the example process **600** would detect an occlusion in the fourth medication delivery interval because the minimum pressure **736** exceeds the pressure threshold P_{THRESH} without any reference to previous measurements in the prior medication delivery intervals **702**, **712**, and **722**.

FIGS. **8-9** illustrate data from a clinical trial of an example medication delivery system **100** to evaluate efficiency of basal/bolus infusion from commercial infusion pumps. A patient was fitted with infusion sets having a sensor **310** to measure pressure to determine occlusions. Generally, pressure data was measured at a rate of 1 Hz and fixed amounts of medication were delivered in 3 minute intervals. Generally, the pressure data was analyzed by removing noise and spurious measurements, identification of minimum and maximum measure pressures, and flow was determined. For example, to capture the first peak, a second derivative of the pressure was calculated from the data illustrated in FIG. **8** and the minimum value within 160 seconds of the maximum pressure. The minimum values after the 160 second window were also recorded for further evaluation as illustrated in FIG. **8**.

After determining the maximum and minimum pressures, the delivery status for each pulse (i.e., medication delivery) was determined by comparing the weighted average of the maximum and minimum pressure of the second prior pulse as described above. In the example illustrated in FIGS. **8** and **9**, it was determined that comparing the immediate prior pulse did not provide a robust indication of flow status in the fluid path. Further, a threshold pressure of 3 psi was set to indicate that an occlusion has occurred in the flow path. During the clinical evaluation, in the event that an occlusion occurred, it was determined that the medical fluid was still stored in the fluid path. As illustrated in FIG. **9**, a delivery factor indicates the number of medication boluses delivered in an interval. Thus, if medication fluid was flowing, the delivery factor would be 1. However, in the event and occlusion occurred, the delivery factor would be zero. Moreover, if an occlusion previously occurred and medication fluid was flowing again, the delivery factor would be greater than 1. Thus, in some examples, the medication delivery system **100** may also determine the number of medication intervals delivered to the user based on previously detected occlusions. As illustrated in FIG. **9**, the medication delivery system **100** determines successful delivery of medication at point A. However, using the measured data at point B, determines that an occlusion is occurring, thereby having a delivery factor of zero. As further illustrated in FIG. **9**, however, temporary occlusions may work themselves out. One such temporary occlusion is illustrated by the pressure over-time-curve s just past point B of FIG. **9**. As shown, pressure increased with each pulse before, during, and after point B, but then pressure normalized, indicating that the temporary occlusion was resolved.

As described above, reliance on force data from the piston during axial movement is not necessarily correlated with flow of the medication fluid. Further, sensitivity in such as system is reduced as the fluid pressure may be masked by the dominating forces associated with static and dynamic frictional forces in the delivery mechanism, that is, the piston of the reservoir. As such, relying on force data from the piston alone detects occlusions much later or not at all compared to an in-line pressure measurement according to an embodiment of the present invention. The exemplary medication delivery system described above advantageously detects occlusions by directly measuring the pressure in the fluid path. Further, the medication delivery system is sensitive to changes in pressure over a short period of time by relying on recent pressure data to determine if suitable amounts of fluid are being delivered. Thus, the medication delivery system reduces the time to detect occlusions by using recent pressure data in conjunction with higher sensitivity to the actual fluid pressure apart from forces present in the fluid delivery mechanism.

Because the pressure is typically measured proximate to the delivery location, effects arising from compression and/or expansion of elastomeric and/or flexible elements, such as tubing, septa, and so on, are detected rapidly. That is, reliance on peak pressure P_{MAX} alone may not account for changes in the fluid path. For example, a partial kink in the tubing would raise the minimum pressure and the examples described in detail above would quickly detect the partial occlusion and provide an indication if corrective action is required to maintain integrity of the medication delivery system **100**.

However, measuring pressure proximate to the delivery location is beneficial for flow-based measurements. In some cases, pressure upstream from the delivery location may not be adequately detected as a result of decay in the pressure at the delivery location relative to the occlusion. Accordingly, another example may implement multiple fluid detectors **125** along or within the fluid path to detect the flow of the medication fluid at several positions in the fluid path, thereby allowing differential comparison of pressures along the fluid path to detect the location of the occlusion and facilitate medical fluid delivery. In yet other examples, a single fluid detector **125** may be implemented at any point along the fluid path.

Further, reliance on only peak pressure may not detect occlusions in the event that the minimum pressure is low. However, the medication delivery system described herein is sensitive to both low pressure and high pressure by eliminating the impact of potential forces experienced by the piston on detection sensitivity and relying on the pressure in the fluid path.

In other examples, the fluid detector **125** may be implemented in continuous or temporary delivery of a medication fluid or fluid sampling or withdrawal from a patient's body via any therapeutic device, such as IV delivery of a medication fluid, a syringe, a catheter set, an infusion set hub, a pen needle, or the like. FIG. **10** illustrates peak pressure of fluid pulses flowing through an IV catheter over time. Thrombus formations that formed in the IV catheter impeded fluid flow as time increases, which consequently increased the peak pressure. Thus, in the example of an IV catheter, the fluid detector **125** could detect an occlusion to prevent potentially dangerous consequences for the patient.

FIG. **11** illustrates a molded needle hub **1105** that is fastened to a needle barrel **1110** to form a syringe **1115** and is configured to communication with a fluid feedback device. The molded needle hub **1105** includes a fluid detector **125** integral therein to detect any suitable fluid characteristic such as pressure, force, and so forth. In such an example, the fluid detector **125** includes a sensor for sensing the fluid characteristic and further devices to enable to communication with the fluid feedback device, which displays the fluid characteristic.

The fluid feedback device is configured to receive information from the fluid detector **125**, process the information to determine if a flow deviation is occurring that could affect the treatment of the patient and provide an indication if a flow deviation is occurring. In other examples, the fluid feedback device may be configured to stop the medical fluid communication, such as an IV delivery system for example. In the event that the fluid feedback device determines that there is a flow deviation that may affect the patient, the fluid feedback device provides an alarm to indicate that the flow deviation exists. In the example of FIG. **11**, the fluid feedback device may be implemented via a touch-sensitive tablet computer that executes an application to display the processed feedback information, however any suitable device could be used, including a tablet computer, a personal computer, a proprietary device for displaying the received information, or the like.

FIG. **12** illustrates an example process **1200** to detect a flow deviation in any suitable medical fluid communication system. Initially, the example process **1200** begins with the communication of a medical fluid, such as blood, urine, antibiotics, glucose, electrolytic solutions, and so on, at step **1205**. At step **1210**, the fluid feedback device transmits an instruction to the fluid detector **125** to begin measuring the fluid and begins receiving measurements from the fluid detector at step **1215**.

Using the receiving measurements, the example process **1200** determines if a flow deviation is occurring at step **1220**. For example, the example process **1200** may implement the process **600** discussed in connection with FIG. **6** to detect a flow deviation. In other examples, the flow deviation at step **1220** could be determined by comparing the received measurement to a static or dynamic threshold. In other examples, a weighted average may be computed using a decaying average and compared to a threshold or a first and/or second derivative of the previous data and compared to a threshold. In the event that a flow deviation is detected at step **1220**, the example process **1200** generates an alarm to indicate that a flow deviation is occurring at step **1225**. In other examples, the medical fluid communication may be discontinued at step **1225**. After generating the alarm at step **1225** or if the no flow deviation is detected at step **1220**, the example process **1200** determines if medication delivery continues at step **1230**. If the medical fluid communication continues, the example process returns to step **1215** to continue measuring and monitoring the flow of the medication fluid. If the medication delivery has ended at step **1230**, the example process ends.

As described above, timed or scheduled replacement of PIVC catheters may be removed prematurely, thereby increasing the cost of medical treatment. The examples described above allow the medical fluid communication system to detect and provide an indication that a flow deviation occurs and, as such, the PIVC catheter should be replaced to ensure proper communication of medical fluids with the patient.

In other examples, a temperature sensor and a pressure sensor may be used in conjunction because temperature and pressure are correlated. Generally, it may be beneficial to measure the temperature in the fluid path in the event that the temperature of the medication fluctuates, thereby allowing temperature compensation to facilitate the detection of occlusions. Further, a force sensor may be implemented outside the fluid path such as, for example, a drive mechanism that connects a servo motor to the piston. In other examples, a fluid volume sensor may be implemented to detect the volume of fluid passing in the fluid path.

While the invention has been shown and described with reference to certain embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method of detecting occlusions in a medical fluid communication system comprising a fluid reservoir, a fluid path connected between the fluid reservoir and a patient, a fluid delivery device, and a pressure sensor having a sensing surface within the fluid path in contact with the medical fluid for directly measuring a pressure of the fluid within the fluid path, the method comprising the steps of:

measuring pressure of a medication fluid in a fluid path of a medical fluid communication system during a current interval with the in-line pressure sensor directly sensing pressure of the medication fluid;

based on the pressure measurements, determining if a flow of the medication fluid is successful or unsuccessful;

wherein determining if the medication fluid is flowing further comprises:

calculating a minimum pressure of the current interval; and

comparing the minimum pressure of the current interval to pressure data of a previous interval,

wherein the flow of the medication fluid is not successful if the minimum pressure exceeds the pressure data of the previous interval;

wherein the pressure data of the previous interval is based on a calculation of a peak pressure of the previous interval and a minimum pressure of the previous interval; and

wherein the calculation is $W*P_{MAX}+(1-W)*P_{MIN}$, where P_{MAX} is the maximum pressure of the previous interval, P_{MIN} is the minimum pressure of the previous interval, and W is a weighting factor set based on the sensitivity.

2. The method of claim **1**, wherein determining if a flow of the medication fluid is successful or unsuccessful further comprises:

calculating a minimum pressure of the current interval; and

comparing a minimum pressure of the current interval to a predetermined threshold pressure,

wherein the flow of the medication fluid is not successful if the minimum pressure exceeds the predetermined threshold.

3. The method of claim **1**, wherein the previous interval is two or more intervals before the current interval.

4. The method of claim **1**, wherein measuring pressure of a medication fluid comprises detecting the pressure applied to a pressure sensor in a fluid path connected between the fluid reservoir and a patient.

5. The method of claim **4**, further comprising:

if the flow of the medication fluid is unsuccessful, determining if the flow of the medication fluid in the fluid path can be resolved; and

attempting to correct the flow of the medication fluid.

6. The method of claim **4**, further comprising, if the flow of the medication fluid is unsuccessful, generating an alarm indicating an occlusion has occurred.

7. The method of claim **6**, further comprising halting further medication fluid from flowing into a patient until the flow of the medication fluid is resolved by a user.

8. A method of detecting occlusions in a medical fluid communication system comprising a fluid reservoir, a fluid

path connected between the fluid reservoir and a patient, a fluid delivery device, and a pressure sensor having a sensing surface within the fluid path in contact with the medical fluid for directly measuring a pressure of the fluid within the fluid path, the method comprising the steps of:

measuring pressure of a medication fluid in a fluid path of a medication fluid communication system during a current with the pressure sensor directly sensing pressure of the medication fluid;

comparing the minimum pressure of the current interval to a predetermined threshold pressure, wherein the predetermined threshold is based on a calculation of a peak pressure of the previous interval and a minimum pressure of the previous interval wherein the calculation is $W*P_{MAX}+(1-W)*P_{MIN}$, where P_{MAX} is the maximum pressure of the previous interval, P_{MIN} is the minimum pressure of the previous interval, and W is a weighting factor set based on the sensitivity; and

determining if a flow of the medication fluid is not successful if the minimum pressure exceeds the predetermined threshold and determining if the flow of the medication fluid is successful if the minimum pressure does not exceed the predetermined threshold.

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